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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/662,052	09/15/2000	Dangsheng Li	5986/1G098-US1	4993

7590 09/17/2002

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EXAMINER
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ART UNIT	PAPER NUMBER
1634	11

DATE MAILED: 09/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/662,052	LI ET AL.	
	Examiner	Art Unit	
	J. Souaya	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *11-20* is/are withdrawn from consideration.

5)☒ Claim(s) *2-9* is/are allowed.

6)☒ Claim(s) *1 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

DETAILED ACTION

1. Currently 1-20 are pending in the instant application. Claims 1-10 are under consideration and 11-20 have been withdrawn from consideration due to a restriction requirement. The previous restriction requirement is withdrawn with regard to claim 9. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. Any rejections not reiterated are hereby withdrawn. The following rejections are either newly applied (necessitated by amendment) or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

3. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 10 has been amended to include hybridization conditions of high stringency. The specification, at pages 16-17 defines conditions for high stringency hybridization, but further

recites at lines 5-7 of page 17: "hybridization requires that the two nucleic acids contain complementary sequences, although depending on the stringency of the hybridization, mismatches between bases are possible". The specification further acknowledges at lines 7-8 "the appropriate stringency for hybridizing nucleic acids depends on the length of the nucleic acids", however the claim only recites a lower length limitation of 20 nucleic acids. Therefore, although the claim recites high stringency conditions, the claimed nucleic acids (which include an unlimited upper length) encompasses a large number of sequences which include genomic sequences (ie: intronic as well as regulatory sequences), sequences containing mutations, and allelic variants from any source which could hybridize to SEQ ID NO 3 under the specified conditions, but which have not been taught or described in the specification. Further, the specification contemplates at page 18, lines 12-15, "Those DNA fragments with substantial homology to the probe, such as an allelic variant from another individual, will hybridize. In a specific embodiment, highest stringency conditions are used to identify a homologous NRIF3 gene". The specification, however, has not taught or described any such nucleic acids and the single nucleotide sequence of SEQ ID NO 3 is not representative of the large genus of nucleic acids encompassed by the claim. With regard to sequences containing a mutation, the specification contemplates mutants of sequences of the claimed invention at page 18, lines 22-29. It is noted that such mutants encompass a sequence that encodes a protein or polypeptide with an altered amino acid at any position of SEQ ID NO 4, and at the very least, an altered motif of SEQ ID NO 4 as well as altered flanking regions of motifs. As the specification expressly teaches that

it is possible that another region of NRIF3 with the sequence of SEQ ID NO 4 [other than the LXXIL motif] may contribute to the observed receptor specificity of NRIF3 and/or that the specificity is determined by the overall three dimensional structure of NRIF3 (p. 52, lines 16-25), the single mutant with altered functional activity (leucine to alanine mutation of the first leucine in the LXXLL N-terminal motif) disclosed is not representative of the large genus of polypeptides with altered functional activity encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NOS: 3, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable

due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

Accordingly, the specification does not provide a written description of the invention of claim 10.

Response to Arguments

The response traverses the rejection. The response traverses that by amending the claim to call for "high stringency" conditions, only exact matches in sequence are encompassed by this claim. This argument has been thoroughly reviewed but was found unpersuasive as such an interpretation of high stringency conditions is not supported by the teachings in the specification as outlined in the rejection above. Further, the claim is not limited only to "any nucleic acid sequence of greater than 20 nucleotides which is contained in SEQ ID NO:3" as the response indicates at page 7 (last sentence of 2nd full para). The claims encompass a probe with intron and exon sequences as well as sequences which have a single nucleic acid change. For these reasons and reasons made of record in the previous office action, the rejection of claim 10 under 35 USC 112/first paragraph is maintained.

Indefinite

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 1 is indefinite in the recitation of "the isolated nucleic molecule of claim 3 further comprising a sequence" as the claim seems to suggest that the nucleic acid of claim 3 further comprises a sequence which encodes a functional NRIF3 with the indicated function and the LXXIL module, whereas the nucleic acid of claim 3 already encodes a polypeptide with the indicated functions. This rejection can be overcome by making the claim an independent claim and including the limitations of claim 3, such as "an isolated nucleic acid molecule comprising a nucleotide sequence consisting of SEQ ID NO: 3 wherein the sequence encodes a functional...".

B) Claim 1 lacks sufficient antecedent basis in the recitation of "the isolated nucleic acid molecule" as it is unclear if such refers to the isolated nucleic acid sequence of claim 3 which comprises a nucleotide sequence, or to the nucleotide sequence consisting of SEQ ID NO: 3 which is comprised by a larger sequence. This rejection can be overcome by amending the claim as suggested in section A above.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Claims 1 and 10 are rejected. Claims 2-9 are allowable over the prior art.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Patent examiner
Art Unit 1634
September 4, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600